

REMARKS

Claims 1-2, 7-18, 20-25, 28-30, and 34 are pending. Claims 3, 4, 5, 6, 19, 26, 27, 31, 32, and 33 have been canceled. Claims 1, 2, 11, 24, 25 and 34 have been amended. The numbered paragraphs below correspond to the numbered paragraphs of the Official Action. The Applicants respectfully request reconsideration in light of the present amendments and remarks.

1-2. The Examiner has rejected Claims 1, 2, 11, 24, 25 and 34 under 35 U.S.C. § 112, first paragraph, because the specification allegedly did not reasonably enable the invention for preventing stereotypy. While Applicants disagree with the propriety of the rejection, solely to expedite prosecution, Applicants have hereby amended Claims 1, 2, 11, 24, 25 and 34 to reflect that treated animals “minimize the risk of an animal developing a stereotypy.” It is respectfully submitted that the claims as amended meet all the requirements of 35 U.S.C. § 112, first paragraph and that these rejections are now moot.

11. The Examiner alleges that a person of ordinary skill in the art would have considered the disclosure of Winskill *et al* reference (“Winskill”) in combination with the Johnson *et al* reference (“Johnson”), and the disclosure of Winskill in combination with Pagan.

Winskill is concerned with the effect of a foraging device (a modified ‘Edinburgh Foodball’) on the behaviour of the stabled horse. It is disclosed (from the end of page 27 to the beginning of page 28) that the Foodball was filled with a pelleted feed. Each kilogram of the food included 200g fibre (20% by weight) and 27.5g of oil (2.75% by weight).

Johnson relates to behavioural changes in stabled horses given nontherapeutic levels of virginiamycin. Abnormal acidity in the hindgut is caused by rapid bacterial fermentation of

carbohydrate, which leads in particular to the accumulation of lactic acid. Virginiamycin is an antibiotic that is specifically active against bacteria that ferment carbohydrate. In contrast, stomach acidity is caused by the secretion of hydrochloric acid into the stomach. Thus, virginiamycin controls hindgut acidosis, but is not expected to have any effect on stomach pH. Johnson also refers (on page 139, right column, second paragraph) to work by Willard in which neutralising the acidity of the hind-gut of horses by administering sodium carbonate to the caecum lowered the incidence of stereotypic behaviour.

Even if a person of ordinary skill in the art had thought to combine the disclosure of Winskill and Johnson and add virginiamycin to the pelleted feed used in the Foodball, a composition comprising fat, fibre, and a stomach antacid would not have been formed since virginiamycin is not a stomach antacid. Neither Winskill nor Johnson discloses a link between stomach acidity and performance of abnormal behaviour (the Applicants have previously submitted evidence that the skilled person would not have thought from disclosure of a link between hind-gut acidity and performance of abnormal behaviour that stomach acidity could also be associated with such behaviour). Thus, the skilled person would not have thought to replace virginiamycin with a stomach antacid.

If a person of ordinary skill in the art had thought to combine use of the Foodball disclosed in Winskill with administration of sodium carbonate, they would not have added sodium carbonate to the feed in the Foodball. Administration of sodium carbonate to reduce acidity in the hind-gut was carried out by caecal infusion, not oral administration (see Willard, page 87, lines 3-4 of summary). Oral administration of sodium carbonate would not be expected to have any effect on hind gut acidity (the Applicants submitted evidence of this in the previous

response). Thus, sodium carbonate would have been administered separately, directly to the caecum, and a composition falling within the scope of the claims of the present application would not have been formed.

Pagan relates to treatment of gastric ulcers in horses. It does not contain any disclosure relating to treatment of stereotypic behaviour, or of a link between gastric ulcers and performance of stereotypies. Winskill also contains no disclosure of a link between stomach acidity and abnormal behaviour. Consequently, it is respectfully submitted that there is no motivation for the skilled person to combine the disclosures of these documents.

12. The Examiner has rejected claims 1, 2, 4 and 6-8 as allegedly obvious under 35 U.S.C. § 103(a) as being unpatentable over Inoue et al. Claim 1 and claim 2 have been further amended to include the features of previous claims 3 (fat in an amount from about 5% to about 20% by weight of the composition), 5 (neutral detergent fibre in an amount from about 15% to about 70% by weight of the composition), and 6 (at least some of the fibre is chopped fibre).

The Examiner states that Inoue teaches the composition of claims 2, 4 and 6 except that Inoue does not refer to the composition as pharmaceutical composition. The Examiner says that it would have obvious to prepare a composition comprising calcium and/or iron nutritional additives and oil palm fronds analyzed to comprise fat and fiber and protein and vitamin E and water and to refer to the composition as pharmaceutical composition, with the expectation of providing healthy stomachs to animals upon administration. Applicants respectfully disagree. The art does not teach that vitamins and/or nutritional additives to palm fronds relieve stomach acid in the way that a stomach antacid would. Thus it is respectfully submitted that Inoue does not provide motivation to modify its composition as recited in amended claim 1.

Just as Inoue does not disclose the presence of a stomach antacid, it also does not disclose the specified amounts of fat and fibre. There is no disclosure of any advantage associated with the presence of fat in the animal feed disclosed in Inoue. Consequently, there is no motivation for the skilled person to increase the amount of fat present. Accordingly, it is respectfully submitted that it would not have been obvious for a person of ordinary skill in the art to modify the composition disclosed by Inoue to provide a composition within the scope of amended claim 1.

13. The Examiner has rejected claims 3-6 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Winskill. These claims are no longer pending. However, the elements of claims 3, 5, and 6 have been added to independent claims 1 and 2. Accordingly, the Applicants have addressed the Examiner's rejection below.

The Examiner states that Winskill teaches the composition of the invention except that Winskill teaches 6.7% oil in the composition and the invention recites fat. However, the composition also differs in that it contains a stomach antacid along with the fat and fibre. As explained above, there is no disclosure in Winskill (or Johnson, or Pagan) of a link between stomach acidity and performance of abnormal behaviour. Winskill is instead concerned with a link between the inability of stabled horses to express foraging behaviour and the performance of stereotypies. Consequently, there is no incentive for a person of ordinary skill in the art to modify the feed used in the Foodball. In particular, there is no motivation for the skilled person to include a stomach antacid, to increase the amount of fat and fibre, or to include chopped fibre.

14. The Examiner rejects claims 9 and 10 under 35 US.C. 103(a) as being allegedly unpatentable over Winskill in view of Johnson, further in view of Pagan.

The Examiner says that it would have been obvious to use the composition of Winskill to treat stereotypic behaviour and to incorporate antacids of Johnson or Pagan with the expectation of reducing the acidity of the hindgut. However, if a person of ordinary skill in the art had considered the disclosure of Winskill in combination with Johnson, they could only have been motivated to add virginiamycin to the feed disclosed in Winskill, or to administer sodium carbonate to the caecum in addition to oral administration of the feed. This would not have resulted in a composition within the scope of any of the claims of the present application. Because there is no disclosure in either of these documents of a link between stomach acidity and abnormal behaviour, a person of ordinary skill in the art would not have modified the feed disclosed in Winskill to include a stomach antacid.

Pagan relates to treatment of gastric (i.e. stomach) ulcers in horses. There is no disclosure in this document that gastric ulcers are associated with performance of stereotypies, or of treatment of stereotypic behaviour. Winskill discloses that use of behavioural enrichment devices could have a possible role for the treatment or prevention of stereotypic behaviour – page 34, second paragraph. However, there is no disclosure that stereotypic behaviour may be improved by use of stomach antacid. Thus, a person of ordinary skill in the art would not have been motivated to add stomach antacid to the feed disclosed in Winskill based on the disclosure of Pagan.

In short, a person of ordinary skill in the art would not have been motivated by the disclosure of the cited prior art to modify the feed disclosed in Winskill to include a stomach antacid, to increase the amount of fat and fibre in the feed, or to include chopped fibre.

15. The Examiner has rejected Claims 11-18, 22, 23, 28-30 and 34 under 35 U.S.C. § 103(a) as being allegedly unpatentable over Johnson and Winskill and further in view of Pagan.

Johnson refers to work by Willard in which the incidence of stereotypic behaviour in horses was lowered following caecal administration of sodium carbonate to neutralise acidity of the hind-gut. The sodium carbonate administered could not have reached the stomach, and so would have had no effect on stomach acidity. Johnson also discloses that dietary supplementation with Founderguard (which contains the antibiotic virginiamycin) reduced abnormal behaviour in horses. This is stated to be due to reduced acidosis in the hindgut. It was explained in the previous response that Founderguard is not expected to have any effect on stomach acidity. Thus, there is no disclosure in Johnson (or Willard) of treating stereotypy by controlling stomach pH.

There is no disclosure in Johnson or in Winskill of a link between stomach acidity and abnormal behaviour. Consequently, the skilled person would not have modified the methods disclosed in either of these documents to treat stereotypy by controlling stomach pH.

Similarly, there is no disclosure in Pagan that treatment of gastric ulcers will have any effect on stereotypy. Thus, the skilled person would not have modified a method of treating stereotypy in which hind-gut acidity is controlled by caecal administration of sodium carbonate to use instead a stomach antacid that would not have any effect on hind-gut acidity.

16. Claims 24 and 25 are rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Johnson and Winskill in view of Pagan.

The Examiner notes that Johnson suggests a relationship between pH or acidity of the hindgut and behavioral responses. However, neither Johnson, Winskill, nor Pagan disclose a

link between stomach acidity and performance of abnormal behaviour, and in particular Pagan does not disclose that treatment of gastric ulcers will have any effect on stereotypy. It is respectfully submitted that the skilled person would not have appreciated from disclosure that the link between hind-gut acidity and performance of abnormal behaviour in Johnson would have suggested that treatment of stomach ulcers would have any effect on performance of stereotypy, let alone with a reasonable expectation of success. Moreover, as the Examiner states, the combined teachings do not teach treatment of ulcers.

17. The Examiner objects to claims 20 and 21 as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The Applicants consider that the claims as amended are patentable over the cited prior art, and so has not restricted the broadest claims to the subject matter of claims 20 and 21.

CONCLUSION


The Examiner has once again alleged that Applicants are required to amend the application to indicate that this case is a 371 of PCT/GB99/03288. Applicants respectfully submit that no such requirement exists and that in fact the USPTO advises against such practice. The Examiner is invited to contact Carol Bidwell of the USPTO Office of PCT Legal Administration (carol.bidwell@uspto.gov) to confirm the undersign's understanding.

Applicants respectfully submit that each of the rejections and objections raised in the November 5, 2003 Office Action have been addressed, and that the application is in

condition for allowance. Accordingly, it is respectfully requested that the amendments be entered and the case passed to issue.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our address given below.

Respectfully submitted,



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